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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/330,629	06/11/1999	CLAUDIA CHERNEY STEWART	JG-RP-4796	9658

26418 7590 09/29/2003

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	25

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/330,629	STEWART, CLAUDIA CHERNEY	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-53* is/are pending in the application.

4a) Of the above claim(s) *15-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 15-53 are pending.

Claims 15-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Restriction requirement was set forth in the previous office action in the parent application.

Applicant's amendments filed June 30, 2003 have been entered.

The outstanding rejection under 35 USC 112, second paragraph is withdrawn in view of the amendments filed June 30, 2003.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 20 of copending Application No. 09/611,286 (hereinafter '286). Although the conflicting claims are not identical, they are not patentably distinct from each other because '286

discloses the same method of prophylaxis the transmission of HIV infection to the recipient. Even though '286 does not expressly disclose the specific herein claimed dosage and regimen of the metallo-cobalt compounds, such adjustment of dosage and regimen would have been obvious to one of ordinary skill in the art at the time the invention was made. One of ordinary skill in the art would have been motivated to optimize the dosage and regimen as recited in the instant application since the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dori (WO93/11140) in view of Cooper et al. (US Patent 4,242,359), references of record in the parent application and Field (Virology, page 26-27, Lippincott-Raven, 1996) and Merck Manual, 16th ed., 1992, pages 49-55.

Dori teaches the method of treating viral infection and decreasing viral titer broadly by topically administering the metallo-organic cobalt compounds, including

compound No. 96 in the instant specification, with a concentration of 0.5 to 10mg/ml (0.05 to 1% by wt) (See page 13, line 16-19; page 19-27, experiment 1-7; claims 1 and 11). Dori also teaches the dosage form of the metallo-organic cobalt compounds may be ointments, salves, and creams (See page 12, lines 16-17). Dori also teaches the metallo-cobalt compounds are useful in treating viral infection broadly, especially for viruses which are well-known in the art, such as listed in Field et al.,, Virology (See page 11, line 19-page 12, line 4).

Dori does not expressly teach the method of prophylaxis for Human Immunodeficiency Virus (HIV) infection by topically administering the metallo-organic cobalt compound No. 96 in the instant specification to the site on the subject which is exposed to the HIV. Dori also does not expressly teach the method of using a condom as an applicator to topically apply the compound No.96.

Cooper et al. teaches a method of topical administration of a medical agent by applicators including a condom is known in the art (See abstract and col. 8, line 40-44).

Field teaches the common viral pathogens in human (See Table 4 in page 26-27).

Merck Manual teaches employing anti-infective agents (both antiviral and antibacterial) in antimicrobial chemoprophylaxis as common practice in the pharmaceutical field (See pages 49-55).

Therefore it would have been obvious for one of ordinary skill in the art at the time the invention was made to topically administer the instant compounds to the site on the subject by using a condom as an applicator for the prophylaxis of HIV infection.

One of ordinary skill in the art would have been motivated to utilize the instant compounds for the prophylaxis of HIV infection because the compounds of Dori are known to be effective in treating viral infections and decreasing viral titer, broadly. It is therefore reasonable to expect the very same compounds, including compound 96, to be useful in prophylaxis, or reduction in the incidence of, any viral infections including those caused by HIV strains since, based on Field, HIV1 and HIV2 are known to be pathogenic to human since such metallo-organic compounds can be used to reduce the number and thereby the incidence of HIV.

Furthermore, one of ordinary skill in the art would have been motivated to topically administer the instant compound by using a condom as an applicator because the method of topical administration of pharmaceutical actives by applicators on to the site that may exposed to the HIV infection, such as the vagina, including a condom is known in the art.

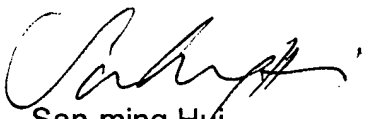
Response to Arguments

Applicant's arguments filed June 30, 2003 averring the cited prior art's failure to provide motivations for the use of antiviral therapeutic agents as prophylactic use have been fully considered but they are not persuasive. it is considered common practice in the pharmaceutical field to use antimicrobial agents for chemoprophylaxis of infection in high risk patients. The cited prior art clearly provide motivation to employ the herein claimed therapeutic agents for prophylaxis of HIV infection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



San-ming Hui
Patent Examiner
Art Unit 1617